

ment of 35 USC 112.

Applicants further respectfully request reconsideration of the Examiner's rejections as set forth above for the reasons presented below. Moreover, applicants acknowledge with gratitude the interview which the Examiner granted on 25 March 1981 during which the substance of the subsequent argument was set forth.

SUMMARY OF THE RESPONSE

The limitation in claims 1-6 that the compositions "consist essentially of" prostacyclin salts is a judicially accepted -- and PTO condoned -- means of indicating the salts are claimed only in essentially chemically pure form. This limitation does not render the claims indefinite, but rather distinguishes the compositions from impure prior art or naturally occurring forms. Additionally the amended version of claim 6, specifying both a use and the amount of the prostacyclin salt in the pharmaceutical composition meets the Examiner's 35 USC 112 rejection in this regard.

The double patenting rejection over either the claims in the parent application, S.N. 819,940, or the count of Interference 100,116 represent at most an "obviousness-type" double patenting situation, not a "same invention" double patenting since the purity limitation in the claims in this application significantly narrow them from the compound per se claims of both S.N. 819,940 and the interference count.

As regards the S.N. 819,940 claims, the filing of a terminal disclaimer in S.N. 819,940 is proffered at the time post-interference ex parte prosecution is commenced.

The double patenting rejection over the count more properly is a prospective rejection on the grounds of (a) interference estoppel or (b) obviousness under 35 USC 102(g)/35 USC 103 which would arise only should priority be awarded adversely on the count of the interference.

Interference estoppel cannot arise unless the claims here presented either are directed to the subject matter of counts lost in the interference or subject matter which could have been contested in the interference, but was not. Essentially pure prostacyclin salts are not the subject matter of the count -- i.e., are not the compound per se, and no estoppel arises. Moreover, in order to have contested priority on the essentially pure prostacyclin salts in the interference, the patentability of such subject matter to all parties would

need to have been demonstrated under 37 CFR 1.231(a)(2). This was impossible in view of the final rejection of the salts in any and every form by the Examiner in the Moncada application over the Johnson et al. reference. Since the issue could not have been raised, an estoppel based on it cannot arise.

Should priority on the count be awarded adversely, then only so much of the count as Moncada reduced to practice in the United States will represent "prior invention" under 35 USC 102(g) which is available as "prior art" under 35 USC 103. This "prior art" is, however, at most limited to prostacyclin itself (not a salt) prepared by biosynthesis according to Example 1 of Moncada's U.S. and U.K. applications. Whatever inference of prima facie structural obviousness arises is rebutted by the non-enablement of those of ordinary skill in the art to make the essentially pure salts given only the biosynthetically derived prostacyclin. In the absence of either interference estoppel or 35 USC 102(g)/35 USC 103 obviousness over a lost count, then no double patenting over the count can arise.

Finally two equitable considerations are present. First the sole purpose of an interference proceeding is to determine which of two applicants is entitled to the patent on a single invention. In the absence of common patentable subject matter, an interference count should not stand in the way of a patentably distinct claim being allowed to one interfering party, regardless of the interference outcome. Second, the public has an interest in the early issuance of claims directed to such patentably distinct subject matter since the uncertainty over the content of the patent rights as well as the duration of those rights is settled expeditiously.

DETAILED COMMENTS

I. "CONSISTING ESSENTIALLY OF" DEFINES A PURITY LIMITATION IN THE CLAIMS.

Claims 1-5 define compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin. For example, claim 5 refers to a composition of matter which is essentially sodium prostacyclin as a free-flowing powder. The Examiner has nonetheless rejected these claims as being indefinite, particularly in not specifying what the "other ingredients" are in those compositions of matter. The language "consisting essentially of" does not, however,

render the claims indefinite, but defines the subject matter of the claims as being essentially chemically pure.

The CCPA has clearly indicated in In re Garner (1969), 56 CCPA 1289, 412 F.2d 276, 162 USPQ 221 (a copy attached), that

"[T]he 'consisting essentially of ...' terminology would, as the Board pointed out, exclude additional unspecified ingredients which would effect the basic and novel characteristics of the product defined in the balance of the claim." (162 USPQ 223)

The Examiner's query as to the specification of "other ingredients" is thus not an index of indefiniteness of the claim: the claim language simply excludes the presence of additional unspecified ingredients affecting the identity of the composition as claimed. The language "consisting essentially of" produces a closed-ended, rather than an open-ended claim, i.e., in contrast to a claim employing "comprising" as a transition between the preamble and the body of the claim.

The discovery of prostacyclin (PGI₂) in 1976 provided the newest member of the family of prostaglandins (PG's), the members of which include PGE₂ and PGE₃. PGE₂ and PGE₃ were claimed in United States Patent 3,598,858, a copy attached. Chemically PGE₂ is 7-[3-hydroxy-2-(3-hydroxy-1-octenyl)-5-oxocyclopentyl]-5-heptenoic acid and PGE₃ is 7-[3-hydroxy-2-(3-hydroxy-1,5-octadienyl)-5-oxocyclopentyl]-5-heptenoic acid. Claim 1 of United States Patent 3,598,858 defines PGE₂ as being "sufficiently pure" to meet certain analytical tests, while claim 2 defines pure PGE₃, employing the language "a composition of matter consisting essentially of 7-[3-hydroxy-2-(3-hydroxy-1,5-octadienyl)-5-oxocyclopentyl]-5-heptenoic acid. Both the PTO Board of Appeals and the CCPA had occasion to construe these claims. See In re Bergstrom and Sjoval (1970), 57 CCPA 1240, 427 F.2d 1394, 166 USPQ 256 (a copy attached). The CCPA noted the statements of the Examiner in rejecting these claims (166 USPQ 259):

"In support of [the examiner's] rejection, and in contrast to appellants' contention that both claims are directed not to naturally occurring materials but to pure compounds which do not exist in pure form in nature, the examiner noted that she could not 'determine from the claims exactly what is included or excluded'".

The Court noted that its view of the claim language as well as that of the Board did not support the Examiner's position.

"The Board approached the issue in quite a different manner. At the outset, we observed that it apparently disagreed with the examiner's interpretation of the claims and agreed with appellants that the claims are directed to pure chemical compounds, variously referring in its decision to 'the claimed pure materials,' 'the claimed pure compounds,' and 'the pure products claimed'".

The language "consisting essentially of" therefore has an accepted, even judicially recognized meaning, in the prostaglandin field -- it distinguishes essentially pure materials, which do not exist in nature, from the impure forms which do (or may) exist in nature.

Hence applicants respectfully assert that claims 1-5 are related to the essentially chemically pure pharmacologically acceptable salts of prostacyclin and are claimed in a manner neither indefinite nor failing to identify other unspecified ingredients. Withdrawal of the Examiner's rejection in this regard is therefore respectfully requested.

II. THE AMENDED VERSION OF CLAIM 6 RECITES BOTH USE AND AN AMOUNT OF ACTIVE INGREDIENT.

Applicants have further amended claim 6 in order to avoid the rejection under 35 USC 112. The claim now expressly includes the specific intended use of the pharmaceutical composition and states the amount of the active ingredient in functional language, i.e., requiring that the concentration of the active ingredient be such that administration of a predetermined volume of the composition or administration of the composition at a predetermined rate would result in accomplishing the specified use (inhibition of platelet aggregation). Both the specific intended use and amount of active ingredients in the compositions are described at pages 2-3 of applicants' specification.

III. THE "DOUBLE PATENTING" REJECTIONS ARE IMPROPER.

A. Subject Matter of Clams 1-6 Differs From The Interference Count and The S.N. 819,940 Claim.

The sole remaining ground of rejection is double patenting over the count of Interference 100,116 and claims of applicants' co-pending

parent S.N. 819,940. In this regard, applicants have presented an amendment in S.N. 819,940, a copy attached, which removes from that application all claims except the claim therein corresponding to the count of the interference.

While the claims of the parties (applicants and Moncada) corresponding to the count in Interference 100,116 and the count itself are all characterized by the chemical structure of compounds, for convenience the claims of the respective parties and the count to will be referred to as relating to

- (A) prostacyclin per se (the Moncada claim),
- (B) prostacyclin salts and esters per se (the Johnson claim),
- (C) both prostacyclin per se and prostacyclin salts and esters per se (the Interference Count).

In contrast to per se claims of both parties to the interference and the count of the interference itself, applicants' claims 1-6 are directed to essentially chemically pure prostacyclin salts and pharmaceutical compositions prepared therefrom.

B. The Absence of Any "Same Invention" Double Patenting Permits a Terminal Disclaimer in S.N. 819,940 to Obviate Double Patenting.

There are two distinct types of double patenting rejections. One is the "same invention" type, which means that for the same or substantially the same claims only one patent may issue; the other is an "obviousness" type double patenting rejection, which prohibits a second patent from issuing with claims patentably indistinct from a first issued patent. In the latter case a terminal disclaimer is effective to remove the rejection; in the former case it is not. In accordance with MPEP 804.02, "claims that differ from each other (aside from minor differences in language, punctuation, etc.) whether or not the difference is obvious, are not considered to be drawn to the same invention for double patenting purposes". In the present situation both the count of the interference and each party's corresponding claim describe chemical compounds per se. The claims encompass those compounds regardless of the environment or purity in which the compounds are present. In contrast, the claims in the above application relate to compounds in essentially pure form (or compositions prepared from the compound in essentially pure form). Therefore, there can be no question but that the differences in the claims

relate to more than minor differences in language, punctuation, etc. They are clearly substantive differences.

Thus, the basis for a double patenting rejection, if any, is an "obviousness" type double patenting which can be remedied by a terminal disclaimer. Filing a terminal disclaimer would place the present application in condition for issuance, while issuance of S.N. 819,940 cannot occur prior to the termination of Interference 100,116. Since in such circumstances the present applicatoin would issue prior to S.N. 819,940, a terminal disclaimer should be filed in S.N. 819,940. Accordingly, if the Examiner allows the present claims conditional on the filing of a terminal disclaimer in S.N. 819,940, applicants hereby agree to the filing of such a terminal disclaimer.

C. The Outcome of Interference 100,116 has No Bearing on The Patentability of Claims 1-6 to Applicants.

The "double patenting" rejection over the count of the interference represents the Examiner's shorthand means of rejecting Claims 1-6 conditionally - as being barred (estopped) or "obvious" over the adverse award of priority in the interference. This rejection is asserted to be improper because Claims 1-6 represent a patentably distinct invention from Moncada and represent subject matter unpatentable to Moncada which as such could not have been an issue in the interference.

1. Interference Estoppel Cannot be Applied.

Interference estoppel operates to prevent a party who has lost an interference from obtaining a patent on his claim corresponding to the count of that interference. In this regard the estoppel operates on the actual issue decided by the interference proceeding. Another aspect of interference estoppel also operates to prevent a party who has lost an interference from obtaining a patent on a claim corresponding to a potential issue or count which he could have put in interference but did not. During an interference a party is entitled to raise new issues by submitting motions under 37 CFR 1.231(a)(2) to add or substitute counts. However, in order for such motions to be proper, the party making the motion must meet the following requirement of 37 CFR 1.231(a)(2):

"Each such motion [to amend the issue by adding or substituting new counts] must contain an

explanation as to why a count proposed to be added is necessary or why a count proposed to be added is preferable to the original count, must demonstrate the patentability of the count to all parties and must apply the proposed count to all involved applications except an application which the proposed count originated."

The provisions of 37 CFR 1.231(a)(2) require that the subject matter of any proposed count must be commonly disclosed, i.e., must be applied to the involved applications and must be commonly patentable. Where the subject matter of the count is not actually disclosed by a party or would not be patentable subject matter to that party, the motion under 231(a)(2) would not be proper and the issue could not be raised in the interference proceeding. As such interference estoppel would not arise as to such an issue.

The CCPA has clearly adopted the view that the estoppel does not arise in situations where counts could not be added. For example, in In re McKellin (CCPA 1976), 529 F.2d 1324, 188 USPQ 428, the Court noted that in the situation where the winning party in the interference was a patentee, the losing party was not entitled to present counts not corresponding to the claims of the patentee and therefore could not be estopped for having failed to present such counts. Similarly, in In re Risse (CCPA 1967) 378 F.2d 948, 154 USPQ 1, the CCPA indicated the following at 154 USPQ 8:

"With regard to interference estoppel, the losing party is only estopped to obtain claims which read directly on disclosures of subject matter clearly common to both the winning party in the application and that of the losing party."

As to the claim on appeal in Risse, the Court further indicated the following:

"Although priority of invention as to this species was not actually determined in the interference, priority might have been so determined, since it represents commonly disclosed subject matter. Thus appellants are estopped to obtain a claim that reads directly on this ... species, regardless of whether the compound is the prior invention of another ... in terms of 35 USC 102(g).

...
"The important thing we stress here is that

the mere fact that appellants are estopped by the interference to claim patentable subject matter which is clearly common to both their ... application and that of [the winning party] ... does not necessarily make such common disclosures of one subgeneric invention 'prior art' under 35 USC 102(g) and 103 as to a different subgeneric invention ... even though both subgeneric inventions are embraced within the generic concept disclosed and claimed in appellants' parent application."

From these CCPA decisions, taken together with the requirements of 37 CFR 1.231(a)(2), applicants would not have been able in Interference 100,116 to move to add new counts directed to the subject matter of claims 1-6 unless they could demonstrate the patentability of such subject matter to Moncada. However an examination of the file wrapper of the Moncada application involved in Interference 100,116 clearly indicates that such subject matter was not patentable to Moncada. Specifically, the sodium salt of prostacyclin is disclosed in the Johnson, et al. publication in Prostaglandins 12:915-928 (1976), appearing in the December issue of this Journal. This publication formed the basis for the Examiner's final rejection of Moncada's claims to these pharmacologically acceptable salts of prostaglandins, a rejection which an examination of the file wrapper of the Moncada application and the file of Interference 100,116 indicates cannot be overcome by Moncada.

Exemplary of Moncada's inability to overcome this final rejection are the following considerations which emerge from the examination of Interference 100,116:

(a) The Moncada Preliminary Statement runs 15 pages and contains literally hundreds of pages of supporting documents. The Preliminary Statement is indeed more akin to a declaration under 37 CFR 1.132 than a Preliminary Statement in an interference. The Moncada Preliminary Statement presumably provides an exhaustive account of the activities of Moncada relating to the invention claimed in the Moncada application involved in the interference. While the Preliminary Statement clearly alleges that Moncada reduced to practice the biosynthetic preparation of prostacyclin in accordance with Example 1 of the Moncada application, nothing in the Preliminary Statement even remotely suggests that Moncada conceived of or undertook the preparation of a composition of matter consisting essentially of a pharmacologically

acceptable salt of prostacyclin. The closest which the Moncada Preliminary Statement comes to such an allegation is the statement on page 12 that Dr. Norman Whittaker of the Wellcome Foundation brought a sample of crystalline prostacyclin sodium salt to the United States on 29 November 1976. However, to the extent this represents a reduction to practice in the United States, it clearly neither represents a reduction to practice of an invention by Moncada or a reduction to practice which would inure to Moncada's benefit.

(b) Indeed, rather than regarding Moncada as the inventor of crystalline prostacyclin sodium salt, the Wellcome Foundation, Moncada's assignee, clearly regarded Dr. Norman Whittaker as the inventor of such compositions of matter as well as their chemical (rather than biosynthetic) preparation. In this regard, the file of Interference 100,116 contains two copies of U.K. applications of Whittaker (43445, filed 20 October 1976, entitled "Heterocyclic Compounds", and 53060, filed 20 December 1976, entitled "Esters") which first provide an example of the preparation of the sodium salt of prostacyclin. Indeed, the sole example of the latter application of Whittaker corresponds to Example 7 in the Moncada application. On this basis, compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin appear to be regarded by Wellcome as the chemical inventions of Dr. Norman Whittaker, not an invention of Moncada. Such subject matter would, accordingly, not be patentable to Moncada in accordance with 35 USC 102(f) since the evidence indicates that Moncada "did not himself invent the subject matter" now sought to be patented by Johnson.

(c) The file of Interference 100,116 in a Declaration by Axen presented in support of the Johnson Motion to Dissolve on the Basis of No Interference in Fact indicates at page 7 that Dr. Udo F. Axen of The Upjohn Company "personally delivered a 100 mg sample of prostacyclin sodium salt to Dr. N. Whittaker in Boston, Massachusetts, on 23 August 1976", thereafter providing documentary support for the transmission of "100 mg sodium salt of enol ether (U-53,217A) THIS MATERIAL BE HAND-CARRIED TO ENGLAND BY DR. WHITTAKER". Evidence is also provided in Exhibit K attached to the Moncada Preliminary Statement that Dr. Whittaker not only carried this sample of the sodium salt to England, but actually transmitted the salt to Moncada and his co-workers for biological analysis. The second page of Exhibit K in fact

begins with the introduction "This report covers the work up-to-date on the pharmacology of a synthetic sample of PGX (53,217A)...", indicating an express reference to the code (U-53,217A) which The Upjohn Company employed for prostacyclin sodium salt. Viewing these facts as a whole, either Dr. N. Whittaker (not Moncada) is the inventor of compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin or Dr. Whittaker derived such an invention in August 1976 from materials received of The Upjohn Company.

Viewing the file of Interference 100,116 as a whole, compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin appear not to have been an invention of Moncada and to the extent Moncada might maintain to the contrary such compositions stand anticipated by the Johnson, et al. publication. In spite of the extensive evidence of inventive acts by Moncada recorded in the interference file, nothing indicates either conception, diligence, or reduction to practice inuring to Moncada's benefit of any composition of matter consisting essentially of a pharmacologically salt of prostacyclin.

Turning to the Moncada file wrapper, the only claims in the Moncada application as filed which relate to a composition of matter consisting essentially of a pharmacologically acceptable salt of prostacyclin were original claims 15-19. These claims relate to the free flowing solid forms of the sodium salt of prostacyclin and their preparation by chemical methods, i.e., the sole means by which such compositions have been prepared. Although these claims were in the Moncada application as filed, they were cancelled therefrom by Preliminary Amendment without comment. In view of the analysis of the interference file as set forth above, the reason for the cancellation is obvious: the Wellcome Foundation, Moncada's assignee, obviously regarded such subject matter as the invention of Dr. Norman Whittaker, not the invention of Moncada. Indeed, the disclosure of compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin do, as indicated above, relate to chemistry described in the Whittaker application filed in the U.K. on 20 October and 20 December 1976. Additionally, as the Examiner noted in the ex parte prosecution of the Moncada application, the Moncada priority applications in the U.K. (19384, filed 11 May 1976, 34151, filed 17 August

1976, and 36547, filed 3 September 1976) failed to describe salts of prostacyclin per se, much less such salts as essentially chemically pure materials. Hence the record in the Moncada file wrapper supports the Examiner's final rejection of the Moncada claims to prostacyclin salts over the Johnson, et al. publication as an irrefutable finding of the unpatentability of these claims on the grounds of anticipation.

Because applicants in Interference 100,116 would have been unable to demonstrate the patentability to Moncada of a count relating to compositions of matter consisting essentially of pharmacologically acceptable salts of prostacyclin, such an issue could not have been added to Interference 100,116 and no estoppel can arise based on the failure to raise such an issue. Moreover, the count of the interference, directed to prostacyclin and its salts and esters per se is obviously not the same issue as claims 1-6 directed to essentially chemically pure form of the prostacyclin salts. Thus no actual or potential issue in Interference 100,116 can estop applicants from claiming the subject matter of Claims 1-6.

2. Claims 1-6 are Non-Obvious Over any 35 USC 102(g)/35 USC 103 "Prior Art".

While the question of interference estoppel cannot be raised against claims 1-6, their obviousness or lack of patentable distinctiveness over the count of the interference as 35 USC 102(g)/35 USC 103 "prior art" will arise in the event Moncada is determined to be entitled to priority in the interference. Similarly, the extent to which claims 1-6 are not rendered obvious or are patentably distinct over the count, the award of priority in the interference is irrelevant to the ultimate patentability of this subject matter. Accordingly, a two-fold inquiry arises: First, what if any is the nature of the "prior art" which would arise under 35 USC 102(g)/35 USC 103 in the event applicants are determined not to be entitled to priority, and, second, to what extent would such "prior art" render obvious claims 1-6.

As to the first question, what becomes prior art to applicants is clearly that which was invented and introduced into the United States by Moncada prior to 23 August 1976. As the CCPA stated in Risse (154 USPQ 6):

"We see no reasonable basis for a contention

that an award or concession of priority necessarily makes the complete disclosure of the winning party's application available as prior art, either by itself or in combination with other art, as against the losing party's application."

The Court in Risse determined (154 USPQ 6) that it was necessary to review the winning party's foreign priority applications to determine exactly what had been invented prior to the losing party's effective filing date. As the Court also noted in McKellin (188 USPQ 433):

"We must first determine when and where the subject matter of the lost count was invented in order to ascertain the significance of lost counts with respect to section 102 ...

"... We have recently reviewed the consequences of a concession of priority with respect to the count of an interference. ... Therein we held that in applicant's refusal to copy claims which he could make resulted in a concession of priority ... but the subject matter of those claims is the prior invention of another in this country under section 102(g) and is prior art to that application under section 103. ... This is the legal consequence of a concession of priority which does not depend on when or where the subject matter of the claims not copied was invented. ... However, when as in the present case, priority is awarded on the basis of evidence of record, the law will not infer facts which are contradicted by facts of the record."

Applying these principals to the facts of record, the determination by the Examiner that Moncada was entitled to the benefit of U.K. application 34 151, filed 17 August 1976, for the purpose of priority under 35 USC 119 as regards the Moncada claim corresponding to the count (whether or not it is correct!) is an inherent determination of compliance with the requirements of 35 USC 112 relating to enablement and best mode. Thus the disclosure in these U.K. applications (but only to the extent Moncada introduced such subject matter into the United States) represents the extent to which an "prior art" under 35 USC 102(g)/35 USC 103 would arise as the result of an award of priority adverse to applicants. In other words, the U.K. applications must be regarded as the fullest and best disclosure of the inventive acts undertaken or contemplated by Moncada at the time these applications

were filed. However the disclosure in these applications is limited to the biosynthetic preparation of PGX, essentially the same disclosure as Example 1 of the Moncada application involved in Interference 100,116. Given this disclosure, essentially devoid of any chemical (rather than biochemical) methodology, one of ordinary skill in the art simply would not be enabled to prepare essentially chemically pure pharmacologically acceptable salts of prostacyclin. Indeed an attempt to do so would begin at best with an unknown (at most, an incorrect!) structure for the salts. Because the preparation of such compositions would be non-obvious over such prior art, then the non-obviousness or patentable distinctiveness of this subject matter over the prior art is established in accordance with the doctrine of In re Hoeksema (1968) 55 CCPA 1493, 399 F.2d 269, 158 USPQ 596. The Court in Hoeksema stated at 158 USPQ the following:

"Thus, as we apply the statute to the present invention, we must ask, first what is the invention as a whole? Necessarily, by the elementary patent law principals, it is the claimed compound, but, so considered, unless there is some known or obvious way to make the compound, the invention is nothing more than a mental concept expressed in chemical terms in a formula on paper.

"We are certain, however, that the invention as a whole is the claimed compound and the way to produce it, wherefore appellant's argument has substance. There has been no showing by the Patent Office in this record that the claimed compound exists because there is no showing of a known or obvious way to manufacture it; hence, it seems to us that the 'invention as a whole', which section 103 demands we consider, is not obvious from the prior art of record."

Because the essentially chemically pure prostacyclin salts could not be prepared without reference to appellants' invention of chemical methodology therefor, independent of biosynthetic preparation, no "obviousness" can be inferred from any "prior art" generated by an adverse award of priority in the interference.

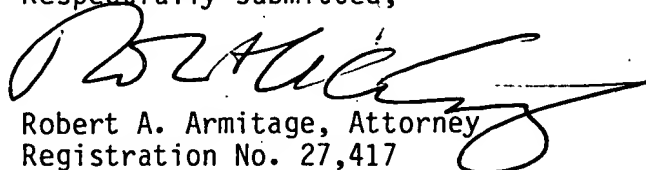
IV. CONCLUSIONS.

The foregoing, therefore, demonstrates that claims 1-6 are not the same invention as the claim pending in applicants' parent application 819,940 and represent a patentably distinct invention over any adverse award of priority in the interference. Moreover, the possi-

bility of interference estoppel is avoided by the unpatentability of the subject matter of claims 1-6 to Moncada. Hence, given the proffer of a terminal disclaimer in S.N. 819,940, the present claims are respectfully asserted to drawn to an invention wholly and independently patentable notwithstanding either the outcome of the claim in S.N. 819,940 or the associated interference 100,116.

Because the sole purpose of an interference proceeding is to prevent two applicants from patenting the same invention, the interference should in no way prevent applicants from succeeding in the present attempt to patent a distinct, but related invention in accordance with claims 1-6. Moreover, the early issuance of claims in the present application furthers the public interest in the prompt issuance of a patent directed to an invention distinct from the count of the interference. Clearly, the delay of issuance of the present application pending the outcome of Interference 100,116 would be unnecessary as well as contrary to the interests of the public. In view of the foregoing, the present application is respectfully asserted to be in condition for allowance and passage of the present application to issue is respectfully solicited.

Respectfully submitted,



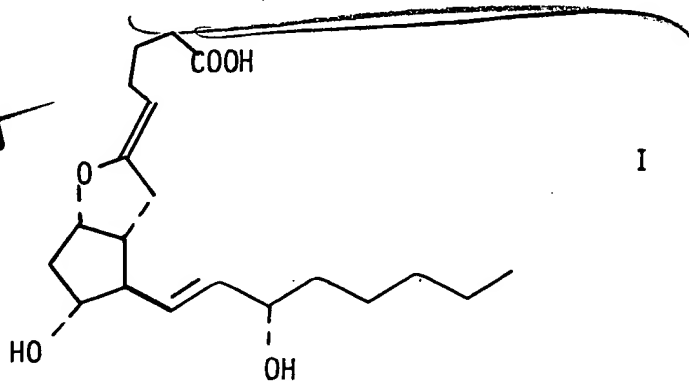
Robert A. Armitage, Attorney
Registration No. 27,417

(616) 385-7345
Kalamazoo, MI 49001
30 March 1981
RAA:nlh

CLAIM 6 (AMENDED)

A parenteral pharmaceutical composition for inhibition of platelet aggregation characterized in being prepared ~~from~~ *from*

(1) a free flowing powder form of the sodium salt of PGI₂, a compound of formula I



and

(2) a conventional pharmaceutical diluent for parenteral formulations, such that the sodium salt of PGI₂ is present in said composition at a concentration sufficient to inhibit platelet aggregation upon administration of a said composition in a predetermined volume or at a predetermined rate.

END

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